

Applicants: Lokhoff et al.
Serial No.: 09/844,628
Page 8

REMARKS

The specification was objected to because there was no brief description of Figure 6. By the above amendment, such a description has been added.

Claims 3, 11, 14, 15 and 20-30 were rejected under 35 U.S.C. 112, second paragraph. These rejections are respectfully traversed.

In particular, claims 3, 11, 14, and 15 were rejected because the Examiner asserts that certain terms were "inferentially claimed" and thus vague. Applicants respectfully assert the claims in question are sufficiently clear for one of ordinary skill in the art to interpret them and as such, a rejection under 35 U.S.C. is improper. MPEP 2173. Furthermore, whether or not the terms in question are inferentially claimed is irrelevant as that is not a proper basis for rejecting a claim in the first place. Should the Examiner maintain such a rejection, Applicants respectfully request specific legal support for making a rejection based upon "inferential claiming". The elements in question are part of the claim, they are clear, and should be examined.

With respect to claims 20-30, the Examiner's issues have been obviated through the above amendments. Applicants request withdrawal of the rejection.

Claims 1, 5, 7-11, 14, 16, 19-21, 25, 28, 29, 31 and 33-35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. in view of Russink. Applicants respectfully traverse the rejection.

As the Examiner is well aware, a proper rejection under 35 U.S.C. 103(a) must present a *prima facie* case of obviousness. Thus, the combination of references must not only teach each and every claimed element, but must provide some motivation within the references as to why such a combination would be made by one of ordinary skill in the art. In the present case, the Examiner has failed to establish a *prima facie* case of obviousness and the rejection is unsupported by the art. As such, the rejection must be withdrawn.

Li et al. teaches a lead having a helical tip electrode having a diameter smaller than the inner lumen and of course, smaller than the lead body. Thus, whether the helical tip is advanced or retracted the diameter is the same. Russink teaches a lead

Applicants: Lokhoff et al.
Serial No.: 09/844,628
Page 9

having a tip electrode and a separate helical fixation member that is larger in diameter than the lead body.

These references are not properly combinable. Other than using impermissible hindsight and Applicants' claims as a roadmap, why would one of ordinary skill in the art combine these two references? In short, one of ordinary skill in the art would not. Li et al. explicitly teaches maintaining the narrowest diameter possible with the use of helical tip that functions as an electrode. Rusink teaches having a separate fixation means (helical tip) and an electrode. Thus, the larger diameter serves to move the fixation means away from the electrode and hence the point of contact of the electrode. The Examiner has taken this as a "motivation" to combine; namely, "[i] would have been obvious . . . modify Li . . . as a means to displace from the immediate electrode the trauma caused to the heart wall be [sic] the helix." How? In Li, the helix is the electrode. Expanding its diameter does not change that. Thus, there is no legitimate reason why one of ordinary skill in the art would be motivated by the Rusink reference to modify the Li et al. device. Thus, the rejection is improper and should be withdrawn.

Even if the two references were combined, the resultant combination does not teach the claimed invention. Claim 1 requires, among other things, "a helix residing within the inner lumen and adapted to be extended beyond the distal end of the elongated body, at least a portion of the helix having a diameter that is larger than the diameter of the elongated body when the helix is extended." Rusink teaches a larger diameter helix that is retained within a dissolvable tip. Thus, if the two references were combined, the Li et al. electrode would be contained within a dissolvable tip as that is the only means taught for achieving the compression of the helical tip to a smaller diameter. There is no teaching in the references as to how to place a helical tip electrode in a smaller diameter lumen and have it expand to a diameter larger than the lead body. The Examiner is not permitted to use Applicants' claims as a roadmap, picking and choosing elements from various references. The cited references must be considered in their entirety. As such, the rejection is unsupported by the art and should be withdrawn.

Applicants: Lokhoff et al.
Serial No.: 09/844,628
Page 10

The remaining claims are allowable for similar reasons. In view of the foregoing amendments and remarks, it is believed that the application is in condition for allowance and notice of the same is respectfully requested.

Respectfully submitted,

Date: 7/1/03



Daniel G. Chapik
Registration No. 43,424
MEDTRONIC, INC.
Telephone: (763) 514-3066
Facsimile: (763) 514-6982



27581